



## Information Sharing - FDA Interpretations

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# What You Will Learn

- Commissioning vs 20.88
- Information Use
- Records Ownership
- State's Responsibility with FDA  
Non-Public Information

**MFRPAlliance**



# INFORMATION SHARING INTERACTIONS:\*

Freedom of Information (FOIA)

Contracts

Cooperative Agreements

Rapid Response Teams

Emergency Response

Memoranda of Understanding (MOUs)

Confidentiality Commitments (Foreign)

Federal Partnership (20.85)

State Partnership (20.88)

Litigation

Press Releases


State/Federal Government Inquiries

\*Not all inclusive

Contact DIDP: [ORAINFOSHARE@FDA.HHS.GOV](mailto:ORAINFOSHARE@FDA.HHS.GOV)

# INFORMATION

## TYPES OF NPI



Commercial  
Confidential  
(CCI)



Trade  
Secret (TSI)



Complanant/  
Whistleblower

## WAYS WE SHARE



Written



Electronic



Oral

## SHARING VEHICLES



- Credential
- Certificate



20.88 ISA



Contract

- 🎯 TSI can be shared under commission & contracts, but use is limited
- 🎯 Sharing is discretionary on FDA's part (e.g., complaints)

# SHARING UNDER COMMISSION: AN UNDERLYING BARRIER



Yes, we can share trade secrets under commission



Major barrier when sharing under commission



Information shared under a commission only used for work directly with FDA



# THE SOLUTION: 20.88 ISA



## Reality

20.88 is more effective agreement

Allows greater flexibility to use FDA information

Allows proactive sharing by FDA

Requires redaction of trade secrets



## Litmus test

What will the information be used for?

State or FDA Action/Authority?

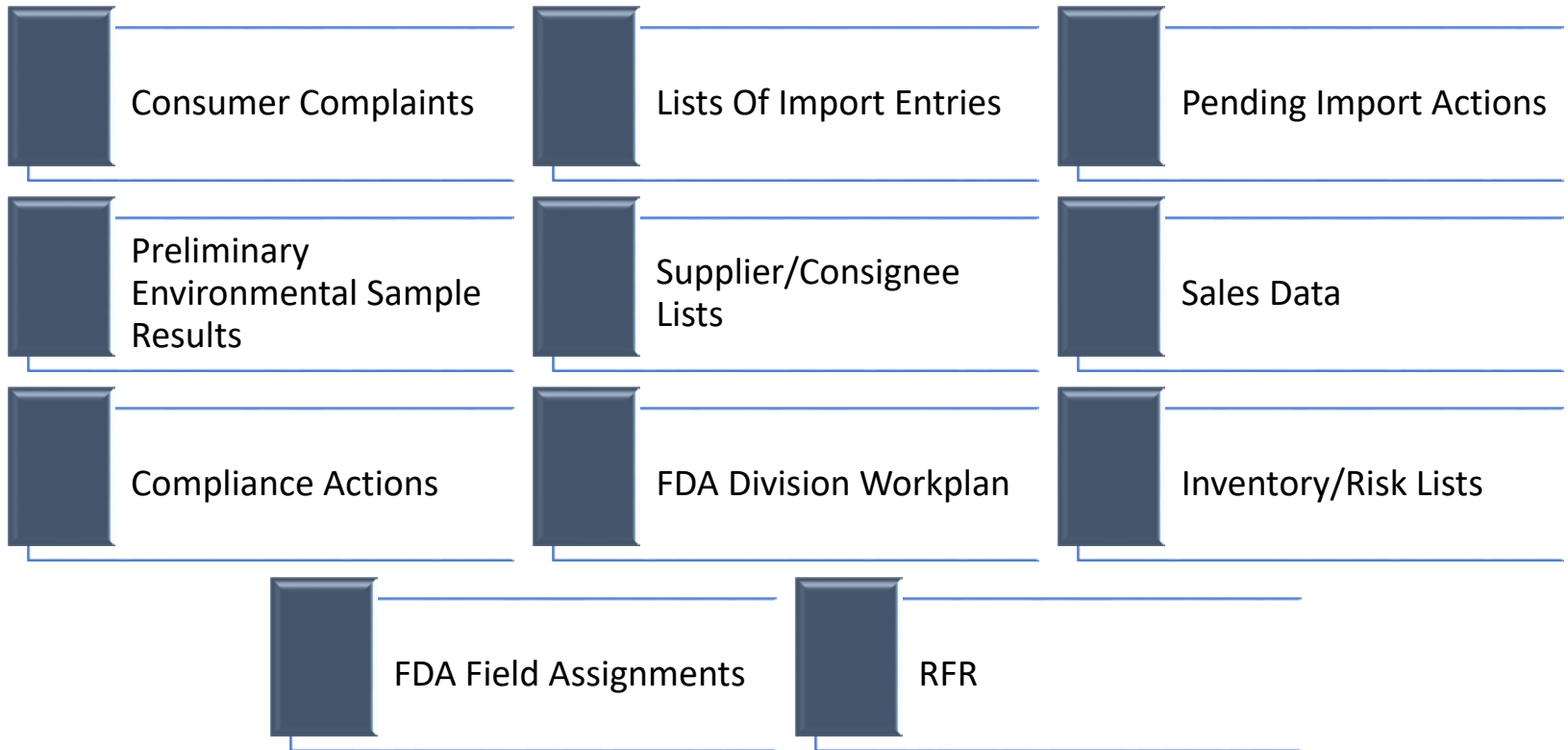


## Commission certificate

Not a stopgap to an inability to obtain a 20.88 ISA

Not effective to share information for state action

# EXAMPLES OF INFORMATION REQUESTED\*



\*All examples must be redacted for TSI

# SHARING UNDER CONTRACT



Used only in direct relation to contract work for sharing FDA reports for contract firms only



Commission certificates aren't required to conduct contract work

- Unless state authority doesn't cover contract work – then need credentials



Allowed to share TSI per regulation



# VEHICLES FOR INFORMATION SHARING

Allows FDA to disclose communications and non-public information (NPI) state & local government counterparts as part of cooperative law enforcement or regulatory efforts

20.88 (STATES)



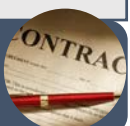
Authorizes state employees to conduct examinations and investigations as FDA employees  
Considered FDA employees

COMMISSION



Allows FDA to share information as outlined in contract

CONTRACT



Commodities Types	Can combine commodities into one agreement	Commodity specific	Specific to contract
Applies to	Anyone who signs confidentiality form accompanied by request letter	Individual only	Covers all working under contract
FDA's Requirement to Share	Discretionary sharing		
NPI Access	Share all NPI <b>EXCEPT TSI</b> <sup>2</sup> Discretionary for PPI/whistleblower	Able to share all NPI (including TSI) Discretionary for PPI/whistleblower	
Further Use of Information	For further State action	Only for work directly for FDA	
Ability to Protect Information	<b>Must agree to protect and not further disclosure outside of group/agency<sup>1</sup></b>		
Regulatory Citations	<a href="#">21 CFR 20.88</a>	<a href="#">21 U.S.C. §372(a)</a> , <a href="#">21 U.S.C. §331(j)</a> , <a href="#">18 U.S.C. §1905</a> , <a href="#">5 U.S.C. §552a</a> , <a href="#">21 CFR §20.88(a)</a>	<a href="#">21 U.S.C. §331(j)</a> , <a href="#">21 U.S.C. §360j(c)</a> , <a href="#">18 U.S.C. §1905</a> , <a href="#">21 CFR §20.88(b)</a> , <a href="#">21 CFR §20.90</a>

<sup>1</sup>Commissioned individuals can only share with same agency office with same commodity endorsement

<sup>2</sup>Device and tobacco CCI is considered TSI and can't be shared under 20.88/20.85 agreements

# PROTECTION RESPONSIBILITIES

## Identification

Clearly identify FDA records as FDA's, even in electronic systems

## Release Internally

Do not release to anyone not covered by agreement information shared under

## Release to Public/Redaction

General practice is not to redact FDA documents under state disclosure/FOI laws for public disclosure. If you receive an FOI/subpoena/request for records that includes an FDA document, or have questions on releasing FDA records (in part or whole) to the public (e.g., press release), contact DIDP or refer requests to FDA FOIA

## Inadvertent Disclosure

Accidents happen! Contact DIDP as soon as you identify an inappropriate release of NPI to mitigate risk.

## State Owned Documents

State can disclose without FDA permission under state disclosure laws

**What if you can't keep FDA-owned records from release?**

# COVERSHEET

**MAINTAIN ON EVERY  
ATTACHMENT FROM FDA**

## Non-public Information Coversheet

**DOCUMENTS ENCLOSED  
Contain  
Non-Public Information**



The enclosed document(s) may contain information prohibited from public disclosure by law. Unauthorized disclosure of non-public information could be a civil or criminal violation and carry consequences for the disclosing official. If you are not the intended recipient or believe that you have received document(s) in error, do not copy, disseminate or otherwise use the information and contact FDA regarding the handling of these document(s). Any request to share this information outside of the intended recipients must be approved in advance by FDA. Contact [orainfoshare@fda.hhs.gov](mailto:orainfoshare@fda.hhs.gov).

# WHO OWNS THE DOCUMENT WHEN CONDUCTED UNDER . . .



20.88 ISA



COMMISSION



COOP  
AGREEMENT  
(CREDENTIAL)

\* Ex: Produce



CONTRACT  
(FDA AUTHORITY)



CONTRACT  
(STATE AUTHORITY)



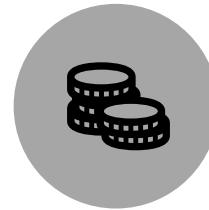
**—STATE MUST CONTACT DIDP BEFORE FURTHER RELEASE—**

# WHO OWNS THE DOCUMENT WHEN CONDUCTED UNDER . . .



COOPERATIVE  
AGREEMENT  
(STATE AUTHORITY)

\* Ex: Produce



GRANTS

**STATE OWNS THE DOCUMENTS**  
(UNLESS SPECIFIED IN AGREEMENT)

# Why do we guard information?

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IT'S THE LAW



PROTECT PUBLIC TRUST

# FINAL TAKEAWAYS



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20.88 information sharing agreements are an effective way to share and use information

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When commissioned **you are an FDA employee**; any information shared under commission can only be used in relation to FDA work

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You don't need a commission certificate to perform contract work

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Federal laws govern the disclosure of FDA records; contact DIDP for requests that affect these records

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States agree to protect FDA information from unauthorized public release. Contact DIDP as soon as you become aware of an inadvertent release.

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Plan requests to allow time for review and redaction

# Public Available FDA Regulatory and Inspection Resources



## Inspections

- [Inspection Classification Database](#): view the classification of inspection outcomes
- [Database FAQ](#)



## Compliance

- [Warning Letters](#): view redacted FDA warning letters
- [Recalls, Market Withdrawals, & Safety Alerts](#): view public information on recalls



## Outbreaks

- [Outbreaks of Foodborne Illness](#): view outbreak investigations reports, and prevention information



## Imports

- [Voluntary Qualified Importer Program \(VQIP\)](#): helps expedite review and import entry of foods
- [Accredited Third-Party Certification Program \(TPP\)](#): helps establish eligibility for participation in VQIP
- [Import Alerts](#)



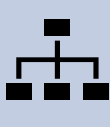
## Datasets

- The [FDA Data Dashboard](#) provides interactive data visualizations and downloadable datasets on inspections, compliance, and imports.



# Contact Information

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